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411

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/050,277	01/15/2002	David A. Schwartz	SOL.004.P	5923
7590	09/21/2004			
David B. Waller David B. Waller & Associates Suite 214 5677 Oberlin Drive San Diego, CA 92121			EXAMINER NAFF, DAVID M	
			ART UNIT	PAPER NUMBER
			1651	
DATE MAILED: 09/21/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/050,277

Applicant(s)

SCHWARTZ, DAVID A.

Examiner

David M. Naff

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 69-72 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 69-72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date. _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1651

DETAILED ACTION

The amendment of 6/15/04 amended claims 70 and 72.

Claims examined on the merits are 69-72, which are all claims in the application.

5 The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

10 Claims 69-72 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

15 The specification does not disclose the biomolecule/polymer conjugate wherein the polymer is poly-L-ornithine.

Response to Arguments

20 Applicants refer to the examples and application 09/815,978 that is incorporated by reference. However, the examples do not disclose poly-L-ornithine. While, poly-L-ornithine may be disclosed in application 09/815,978, there is nothing in this application to indicate that poly-L-ornithine was to be part of the present invention.

Claim Rejections - 35 USC § 103

Claim 69 is rejected under 35 U.S.C. 103(a) as being unpatentable over Koster et al (6,133,436) in view of Monforte et al (6,566,055 B1) and Cook et al (5,783,682), and if necessary in further view of
5 Mirzabekov et al (5,981,734) for reasons in the previous office action of 2/18/04 and for reasons herein.

The claim is drawn to a biomolecule/polymer conjugate wherein the biomolecule is conjugated to the polymer by a hydrazone bond, and the biomolecule is a polynucleotide, oligonucleotide, DNA or RNA, and the
10 polymer is poly-L-lysine, poly-L-ornithine or polyethyleneimine.

Koster et al disclose covalently attaching nucleic acids to beads attached to a solid support (col 3, line 57 to col 5, line 4). A linking group such as polylysine (col 7, line 16) can be used to bind the beads to the support or the nucleic acid to the beads (col 7,
15 lines 12-17).

Monforte et al disclose attaching a nucleic acid to a support using a hydrazone group (col 15, line 60).

Cook et al disclose using a hydrazone connection during nucleic acid synthesis on a solid support (col 10, line 25).

20 Mirzabekov et al disclose using a hydrazone bond to couple a label to a nucleic acid (col 4, line 39).

It would have been obvious to use a hydrazone bond to couple a nucleic acid to polylysine when using the polylysine to couple a nucleic acid to beads as disclosed by Koster et al as suggested by
25 Monforte et al attaching a nucleic acid to a support using hydrazone

Art Unit: 1651

group and Cook et al using a hydrazone connection during nucleic acid synthesis on a solid support. Using poly-L-lysine as the polylysine would have been obvious since this is a form of polylysine that is readily available. The use of a hydrazone bond to couple a nucleic acid to a label as disclosed by Mirzabekov et al, if needed, would have further suggested using a hydrazone bond to couple a nucleic acid to the polylysine of Koster et al.

Response to Arguments

Applicant urges that Koster et al does not bond a nucleic acid to polylysine. However, polylysine can be a linking group to bond the nucleic acid to beads.

Applicant urges that there is no motivation to make the combination by applying the teachings of the secondary references to the primary reference. However, it would have been obvious to use a hydrazone bond in Koster et al for the same reason that Monforte et al and Cook et al use this bond. Knowing that Monforte et al and Cook et al found this bond to be suitable when coupling a nucleic acid would have been motivation. The bond used in the claim is that known for reacting with a nucleic acid, and the claimed combination is merely a combination where the whole is the sum of the parts. How to form an hydrazone bond with a nucleic acid and polylysine would have been apparent from the reactions disclosed by Koster et al and Monforte et al and Cook et al. The references are combined together and must be considered in combination as a whole.

Claim Rejections - 35 USC § 103

Claim 71 is rejected under 35 U.S.C. 103(a) as being unpatentable over Koster et al in view of Cook et al (5,541,307) for reasons in the previous office action and for reasons herein.

5 The claim is drawn to a biomolecule/polymer conjugate wherein the biomolecule is conjugated to the polymer by a oxime bond, and the biomolecule is a polynucleotide, oligonucleotide, DNA or RNA, and the polymer is poly-L-lysine, poly-L-ornithine or polyethyleneimine.

Koster et al is described above.

10 Cook et al disclose using oxime linkages when carrying out nucleic acid synthesis on a solid support (col 9, lines 13-21).

It would have been obvious to use an oxime bond to couple a nucleic acid to polylysine when using the polylysine to couple a nucleic acid to beads as disclosed by Koster et al as suggested by
15 Cook et al using oxime linkages when carrying out nucleic acid synthesis on a solid support.

Response to Arguments

As noted above, Koster et al disclose bonding a nucleic acid to polylysine to link the polylysine to beads. It is clear from Cook et
20 al that an oxime is suitable for coupling a nucleic acid to a support, and it would have been obvious to use this bond to couple a nucleic acid to polylysine in the absence of a new and unexpected result. The bond used in the claim is that known for reacting with a nucleic acid, and the claimed combination is merely a combination where the whole is
25 the sum of the parts. How to use an oxime for bonding a nucleic acid

Art Unit: 1651

with polylysine would have been apparent from the reactions disclosed by Koster et al and Cook et al. The references are combined together and must be considered in combination as a whole.

Conclusion

5 Claims 70 and 72 are free of the prior art.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In
10 the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be
15 calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff
20 whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this
25 application or proceeding is assigned is 703-872-9306.

Art Unit: 1651

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David M. Naff
Primary Examiner
Art Unit 1651

DMN
9/20/04